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10/581,695	07/11/2006	Kazuhito Tanimoto	F-9067	1820

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/581,695

Applicant(s)

TANIMOTO ET AL.

Examiner

P. Kathryn Wright

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/6/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show Fig. 1A, as described in the "Brief Description of the Drawings" section (page 8).

Similarly, there is no description of Fig. 3A in the "Brief Description of the Drawings" section.

2. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because it is not limited to a single paragraph. Applicant should also remove reference to Fig. 3 in the abstract. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The analyzer unit is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claims are directed to an automatic analyzer, however no element is recited to enable the device to function as such.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the terms "high" and "low". These are relative terms which renders the claim indefinite. The terms "high" and "low" are not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree, thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It not clear what Applicant considers "high" and "low" speeds. Furthermore, claim 2 includes the "(for positioning)". These parenthesis should be removed for clarity.

Claim 10 recites the terms "small" and "large". These are relative terms which renders the claim indefinite. The terms "small" and "large" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It not clear what Applicant considers "small" and "large" cross-sectional areas.

In addition claim 10 recites "the connecting part". There is no antecedent basis for this claim. Furthermore, it is not clear what applicant means by the "other side of the connecting part".

Claim 11 recites "the rotational center". There is no antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (US Patent No. 3,586,484).

With respect to claims 1 and 7, Anderson teaches an automatic supernatant analyzer (i.e., includes analytical photometer 22) that utilizes a reaction disk (rotor assembly 1). The reaction disk includes separation cells having a plurality of interconnected chambers 12, 14, 16 therein, and a determination cell (reaction cuvette 9) provided in a same reaction disk 1. The separation cells are formed in an upright position, thus the cells remain upright even during rotation thereof (see Figs.1-6).

With respect to the functional language in claim 1 describing the separation cell formed to prevent a suspension from flowing out during centrifugal separation, Applicant is reminded only structural language is determinative of the metes and bounds of a patent claim. Functional recitations, standing alone, while perhaps helpful in understanding the meaning of a claim and the invention that it represents, cannot be relied upon to distinguish over the prior art. Applicant must establish that what is expressly taught by the prior art does not inherently function in the manner required by the claim.

Nevertheless, Anderson does teach that the separation cell is formed to prevent a suspension from flowing out during centrifugal separation; that is, the passageway 15 is formed such that centrifugal forces prevents passage of the supernatant 31 until the cell 11 is brought to rest so that gravitation forces predominates to cause the supernatant to flow the holding chambers 16. Anderson also teaches that the

separated supernatant in the separation cell is dispensed to the determination cell 9 through passageway 17 upon further rotation of the reaction disk for analysis of any target substance in the supernatant (see col. 3, lines 35-60).

Regarding claim 2, Anderson teaches a single motor 19 is arranged to change the rotational speed at a high speed for rotating the separation cell for separation and a low speed for positioning the determination cell for analysis (see col. 2, lines 69-71 and col. 3, lines 41-47).

With respect to claim 3, the separation cell is provided with an insoluble matter 30 collection zone 14 and with a lid 18 at an upper portion of the separation cell above the insoluble matter collection zone to partially cover the separation cell to prevent the suspension from flowing out during centrifugal separation (Figs. 5-6).

Regarding claims 4 and 5, nothing in the claim structurally distinguishes the so-called "dilution cell" from the "separation cell". Moreover, a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. Figs. 2-6 of Anderson illustrate at least two different sets of interconnected chambers 12, 14, 16 on opposite sides of the assembly 1. Thus, the Examiner contends that one set of chambers 12, 14, 16 can be used as the "separation cell" and the other set can be used as a "dilution cell". As with the separation cells, the dilution cells are kept in upright position during rotation. In addition, the dilution cell is formed to prevent poured dilution solution therein from flowing out during centrifugal separation, and the dilution solution in the dilution cell is arranged to be dispense into the determination cell to dilute the supernatant. That is, the

dilution cell is formed to prevent a suspension from flowing out during centrifugal separation. Specifically, the passageway 15 is formed such that centrifugal forces prevents passage of the dilutant through the passageway 15, until the cell 11 is brought to rest so that gravitation forces predominates to cause the dilutant to flow the holding chambers 16. Likewise, the dilution cell is provided with a lid 18 at an upper portion of the dilution cell to partially cover the dilution cell to prevent the dilution solution from flowing out during centrifugal separation.

With respect to claims 6 and 8, please note that the material worked on (i.e., the suspension is blood, insoluble matter is blood cell or the supernatant is plasma) is of no significance in determining patentability of the apparatus claim. The inclusion of material worked upon by a structure being claimed does not impart patentability to the claims.

10. Claims 9-12, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson et al. (US Patent No. 5,472,671), hereinafter "Nilsson".

Nilsson teaches a separation cell (cuvette 10) for separating an insoluble matter from suspension. The separation cell comprises a shelf (ledge below ref. No. 18 in Fig. 2). The upper portion above the shelf reads on the insoluble matter collection zone (channel 18) and the lower portion below the shelf is considered by the Examiner a supernatant separation zone (cavity 22); see col. 3, line 36- col. 4, line 52 and Figs. 1-2. The cell of Nilsson is provided with a hydrophobic material 20 at an upper part of the cell above the insoluble matter collection zone 18 that can act as a "lid" since it partially

covers the cell to prevent the suspension therein from flowing out during centrifugal separation due to its hydrophobic nature.

The functional language describing the position of the cell during centrifuging does not serve to patentably distinguish in an apparatus claim, however the Nilsson cell is kept in upright position during centrifugal separation (see Fig. 1, which illustrates the cell is rotated about its vertical axis, i.e., in an upright manner).

Regarding claim 10, the insoluble matter collection zone 18 has a "small" cross sectional area and the supernatant separating zone 22 has a "large" cross sectional area so that one side of the both zones are communicated with each other. As best as can be understood, the shelf of Nilsson is provided on the other side of the connecting part.

With respect to claim 11, the shelf is provided in the separation cell pointing toward the rotational center (i.e., the shelf is substantially horizontal; see Fig. 2).

Regarding claim 12, the material worked on (i.e., the suspension is blood, insoluble matter is blood cell or the supernatant is plasma) are of no significance in determining patentability of the apparatus claim. The inclusion of material worked upon by a structure being claimed does not impart patentability to the claims. See MPEP 2115.

Conclusion

11. No claims are allowed.


12. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure as general background information related to Applicant's field of endeavor.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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